

## REMARKS

Claims 1, and 4-11 are pending.

In the aforesaid Office Action, the Examiner rejected claims 1-11 under 35 USC 112, first paragraph, stating, in part, that the limitation “a minority of the volume of the marker is metal solids and a majority of the volume of the marker is nonmetal” does not appear to have support in the originally filed application. The limitation has been deleted from claim 1.

The Examiner rejected claims 1 and 4-11 under 35 USC 103(a) as being unpatentable over Klein et al. (US 5,776,141) in view of Elliott (US 2003/0164063), stating, in part, that Klein et al. teaches a radiopaque marker comprising a polymer loaded with tungsten radiopaque particles, which is loaded approximately 36 volume percent of the marker since it is 90% by weight, and that although Klein et al. fails to teach adding a wetting agent for facilitating encapsulation of said particles by said polymer and the diameter of the particles, Elliott however teaches that to get the high packing densities required to have loadings as high as 36 volume percent of the composition, the mean particle size is between 1 and 10 microns, and teaches specific examples in which the median particle diameter is about 10 microns and 90% of the particles have a diameter less than 18.5 microns, and that a wetting agent such as maleic anhydride graft polyolefin is blended with the polymer as a strength enhancing agent.

The Examiner states that therefore, it would have been obvious that when the mean particle size is within the range of 1-10 microns the maximum diameter of a particle would be about 20 microns.

However, contrary to the Examiner's assertion, the maximum diameter of a particle can be significantly over 20 microns despite having a mean diameter of about 10 microns and a  $D_{90}$  of 18.5. There are a large number of tungsten particles in the large percent solids compositions disclosed by Elliott, and the specific example in Elliott referred to by the Examiner allows for 10% of the tungsten particles to have a diameter greater than 18.5. Therefore, many particles will have a particle size over 18.5, and a substantial fraction will be over 20 microns, given that a typical (e.g., log normal) distribution will have a tail (that is, the tail ends of the distribution profile at which the particle sizes are very big or very small). In contrast, Applicant's claims require that no tungsten particles over 20 microns are present.

None of the references disclose or suggest bounding the maximum absolute (not average) diameter of the tungsten particles, while at the same time requiring an average diameter of 2 microns. Elliott teaches a wide range of particle size distributions for the tungsten particles, including a mean particle size of "more preferably still 2-20 microns, and more preferably still 1-10 microns", and a specific example in which the median particle diameter was about 10 microns and  $D_{90}$  was 18.5 microns. In contrast, Applicant's claimed composition limits the particle size distribution to a narrower range. Elliott clearly allows for more of the small particles (e.g., of 1 micron or less) and more of the large particle (e.g., of greater than 20 microns), and none of the particle size

distributions disclosed by Elliott teach a composition having both the maximum diameter and minimum average diameter required by Applicant's composition.

Therefore, modifying Klein et al. in view of Elliott does not disclose or suggest Applicant's marker having radiopaque particles of a radiographically dense metal disposed within said polymer having an average diameter of at least 2 microns and a maximum diameter of about 20 microns.

As discussed in Applicant's specification, Applicant's composition, having the specified radiopaque particle size and percent loading, provides for the polymer functioning as a continuous binder, and provides an improved catheter radiopaque marker (e.g., high radiopacity in a thin, smooth wall from a processable mixture). As such a configuration is not disclosed or suggested by the high density composites at issue in Elliott, and as Klein et al. does not disclose or suggest how a marker band composition having a radiopaque particle percent loading of as high as 90 weight percent (let alone higher than 90 weight percent) is achieved, the combination of Klein et al. in view of Elliott does not disclose or suggest the embodiment of Applicant's radiopaque marker set forth in claim 1.

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Respectfully submitted,  
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